

K960344

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Exhibit 15. 510(k) Summary

FEDERAL FOOD, DRUG AND COSMETIC ACT  
510(k) SUMMARY  
**DOCUMENT<sup>®</sup> TDM ULTRA Assayed Control, Levels I, II, III**

1. Submitted by: CASCO Standards  
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2. Product Name:

Proprietary Name: **DOCUMENT<sup>®</sup> TDM ULTRA Assayed Control**

Classification Name: Control, multiple analyte, assayed.

### 3. Predicate Device:

Product:	Dade Immunoassay Controls Comprehensive Tri-Level, Levels 1, 2, and 3
Catalog:	Level 1 (B5700-6), Level 2 (B5700-7), Level 3 (B5700-8)
Manufacturer:	BaxterDiagnostics, Inc., Deerfield, IL 60015-4633
Analytes:	ACET, AMI, CARB, DIG, DISO, ETHO, GENT, LIDO, NAPA, PHENO, PHENY, PRIM, PROC, QUIN, SAL, THEO, hTSH, T4, TOB, T3, TU, VAL
Product:	Instrumentation Laboratory TheraChem TDC Therapeutic Drug Controls, Low and High Levels
Catalog:	Low (2841-31), High (2842-31)
Manufacturer:	Instrumentation Laboratory Company, Lexington, MA 02173-3190
Analytes:	METH, VANCO
Product:	Abbott REA Ethanol Serum Control, Levels L, M, and H
Catalog:	9545-11
Manufacturer:	Abbott Laboratories, Abbott Park, IL 60064
Analytes:	ETOH

4. Product Description: **DOCUMENT<sup>®</sup> TDM ULTRA Assayed Controls** consist of three levels of a human serum matrix containing 25 commonly monitored analytes. The formulation design provides a liquid matrix intended for use on automated and semi-automated immunochemistry systems and clinical chemistry systems for the determination of blood acetaminophen (ACET), amikacin (AMI), carbamazepine (CARB), digoxin (DIG), disopyramide (DISO), ethanol (ETOH), ethosuximide (ETHO), gentamicin (GENT), lidocaine (LIDO), methotrexate (METH), N-acetylprocainamide (NAPA), phenobarbital (PHENO), phenytoin (PHENY), primidone (PRIM), procainamide (PROC), quinidine (QUIN), salicylate (SAL), theophylline (THEO), thyroid-stimulating hormone (hTSH), thyroxine (T4), tobramycin (TOB), triiodothyronine (T3), T-Uptake (TU), valproic acid (VAL), and vancomycin (VANCO).

5. Intended Use: This product is intended for *in vitro* diagnostic use as a control product to assess the analytical performance of immunochemistry systems and clinical chemistry systems using methods for the quantitative measurement of the listed analytes. It is intended to provide the necessary control material required by inspection agencies for the evaluation of system performance. In addition, it will provide assistance when troubleshooting chemistry systems, reagent problems and calibration anomalies.

6. Comparison to the Predicate Device:

Characteristic	<b>DOCUMENT®</b> TDM ULTRA Assayed Control	Dade Immunoassay Comprehensive Tri-Level Control	Instrumentation Laboratories TheraChem TDC Therapeutic Drug Control	Abbott REA Ethanol Serum Control
Intended Use	To assess the analytical performance of analytical systems in the quantitative measurement of therapeutic drugs, thyroid function, and ethanol	Assist in monitoring accuracy and precision in clinical assays	Control material for procedures used to quantitate levels of therapeutic drugs and thyroid hormones in serum specimens	Controls for the validation of calibration of the REA Ethanol assay on the TDxFLx, TDx, or ADx
Number of Levels	Three (3): Level I, Level II Level III	Three (3): Level 1, Level 2, Level 3	Two (2): Low, High	Three (3): L, M, H
Type	Assayed	Assayed	Assayed	Assayed
Analytes	25	64	30	1
Volume	5 mL	5 mL	5 mL	4 mL
Matrix	Human serum, Liquid	Human source, Lyophilized	Bovine serum, Lyophilized	Human blood components, Liquid
Dilution	None required	None required	None required	None required
Unopened Stability	Until Expiration Date	Until Expiration Date	Until Expiration Date	Until Expiration Date
Open Stability	30 Days	Varies with analyte following reconstitution	Up to four weeks after reconstitution	Until expiration date
Container	Plastic, Dropper Tip	Glass	Glass	Plastic

## 7. Test Results:

The equivalence for this product was carried out by comparing the inter-assay precision of the listed analytes of the **DOCUMENTI**<sup>®</sup>TDM ULTRA Assayed Control to that of Dade Immunoassay Controls Comprehensive Tri-Level, Instrumentation Laboratory TheraChem TDC Therapeutic Drug Controls and Abbott REA Ethanol Serum Control. The results show that the **DOCUMENTI**<sup>®</sup>TDM ULTRA Assayed Control behaves in a similar manner compared to the predicate devices and is suitable for use as a control for the listed analytes.